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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO.       |
|--|-------------|----------------------|------------------------------|------------------------|
| 10/523,291   | 08/23/2005  | Markus Schumutz      | PN4-32527A                   | 6485                   |
| 1095   | 7590        | 11/09/2007           |                              |                        |
| NOVARTIS<br>CORPORATE INTELLECTUAL PROPERTY<br>ONE HEALTH PLAZA 104/3<br>EAST HANOVER, NJ 07936-1080 |             |                      | EXAMINER<br>JAVANMARD, SAHAR |                        |
|  |             |                      | ART UNIT<br>4133             | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>11/09/2007      | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/523,291 | <b>Applicant(s)</b><br>SCHUMUTZ, MARKUS |  |
|                              | <b>Examiner</b><br>SAHAR JAVANMARD   | <b>Art Unit</b><br>4133                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7, 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 and 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/23/2005</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The Office Action is in response to the 371 of PCT/EP03/08669 filed August 23, 2005. Claims 1-6 and 8 have been cancelled. Amended claims 7 and 9-13 are being examined on the merits herein.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volosov et al. (WO 00/01416) and Benes et al. (EP 0751129A1) in view of Simpson et al. (Trends in Pharmacological Sciences, 1999).

Volosov teaches compounds of formula I wherein R1 and R2 represent an oxo group taken together and where R1 represents H and R2 represents OH, as set forth in claims 7, 9, and 10 (page 5). Volosov teaches these compounds as antiepileptic drugs.

Volosov does not teach compounds of formula I wherein R1 represents H and R2 represents acetoxy. Further, Volosov does not teach the administration of these

compounds for the treatment of tinnitus and other inner ear/cochlear excitability related diseases.

Benes teaches compounds of formula I wherein R1 represents H and R2 represents acetoxy (and its stereoisomers) and that these compounds serve as effective agents in treating epilepsy (page 2, lines 6-48).

Simpson compares tinnitus and epilepsy. Simpson teaches that tinnitus is a form of sensory epilepsy. Simpson teaches that if tinnitus were the result of hyper-excitability within the central auditory system, it would be directly analogous to epilepsy, which is characterized by abnormal discharge of central neurons purported to be linked to the inappropriate activity of the excitatory transmitter glutamate. The  $\alpha$ -amino-3-hydroxy-5-methyl-4-isoxazole propionate (AMPA) and *N*-methyl-D-aspartate (NMDA) receptors implicated in epilepsy are also functionally important in the afferent conduction of sound. Excessive activity at these glutamate receptors leads to neurotoxicity, and it has been suggested that this may be the pathophysiological mechanism responsible for a number of inner-ear diseases. This theory suggests that agents that decrease neural activity, such as anticonvulsants and specific glutamate receptor antagonists, might provide effective tinnitus treatments.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the drugs taught by Volosov and Benes and administered them for the treatment of tinnitus and other inner ear/cochlear excitability related diseases as taught by Simpson being motivated by the reasons mentioned above.

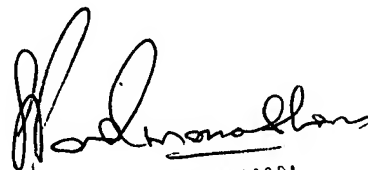
### **Conclusion**

Claims 7 and 9-13 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY STUCKER can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



GREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER